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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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This document supercedes the previous chapter dated June 8, 1999 (DP Barcode D256666). It incorporates additional processing factors from re-evaluation of the processing data, cooking factors obtained from newly submitted open literature studies and recent policy changes concerning the treatment of blended and non-blended food forms in the dietary analysis (HED SOP 99.6, 8/20/99).

MEMORANDUM:

SUBJECT: **Revised Chlorpyrifos Methyl: Residue Chemistry Chapter of the RED.**
PC Code No. 059102. DP Barcode D259808.

FROM: Sarah Levy, Chemist *Sarah Levy*
Registration Action Branch 1
Health Effects Division (7509C)

THRU: Steve Knizner, Branch Senior Scientist *St Knizner*
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TO: Stephanie Nguyen, Chemical Review Manager
Reregistration Branch 3
Special Review and Reregistration Division (7508C)

Attached please find the revised product and residue chemistry chapter of the Chlorpyrifos-methyl Reregistration Eligibility Decision (RED). This chapter has been prepared by Dynamac Corp. under contract to the Agency and has undergone secondary review to reflect the Health Effect Division's (HED) policies.

cc: S. Levy, S. Knizner, G. Bangs, RRB3 files
SJL 11/1/99, SAK 11/1/99
RDI: CM#2, 823E, 305-0783, SJL

CHLORPYRIFOS-METHYL

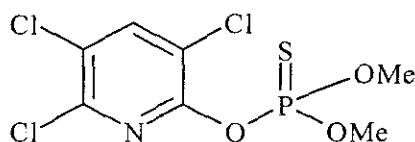
REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 059102

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Chlorpyrifos-methyl



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 059102

INTRODUCTION

Chlorpyrifos-methyl (CPM) [*O,O*-dimethyl-*O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate] is an insecticide registered for use on stored grain crops including barley, oats, rice, sorghum, and wheat. CPM is manufactured by Dow AgroSciences (DAS) under the trade name Reldan®. CPM formulations registered to DAS for use on food/feed crops include one emulsifiable concentrate (EC) formulation. Application of this product is limited to post-harvest treatment of stored grains or grain storage facilities.

REGULATORY BACKGROUND

CPM has been the subject of a petition (PP#0F2423 and FAP#0H5277) proposing tolerances for residues in/on stored grains and livestock commodities that was recommended for approval on April 30, 1985; all current CPM tolerances are based upon this petition. In addition, there is currently one active petition pending (PP#6F3429/6H5506) from DowElanco pertaining to use of CPM on stored corn grain. This petition is currently in reject status based upon deficiencies in label directions and proposed tolerances (DP Barcode D186441, J. Morales, 6/2/93 and DP Barcode D200683, M. Flood, 6/15/94). The information contained in this reregistration eligibility decision (RED) Chapter outlines the current Residue Chemistry Science Assessments with respect to the reregistration of CPM.

Tolerances have been established for residues of CPM and its metabolite 3,5,6-trichloro-2-pyridinol (TCP) in/on barley, oats, rice, sorghum, and wheat grain at 6.0 ppm under 40 CFR §180.419; tolerances for milled fractions (excluding flour) of each of these raw agricultural commodities (RACs) have been established at 30 ppm (rice and wheat), 90 ppm (barley and sorghum), and 130 ppm (oats) under 40 CFR §185.1050 and §186.1050. Tolerances have also been established for residues of CPM in milk and milk fat at 0.05 and 1.25 ppm, respectively.

eggs at 0.1 ppm, and in meat, meat-by-products (mbyp) and fat of cattle, goats, hogs, horses, poultry and sheep at 0.5 ppm [§180.419].

During the reregistration of chlorpyrifos, the Agency determined that the metabolite TCP, common to both chlorpyrifos and CPM, is no longer considered to be of toxicological concern (E. Doyle, TOX Branch memo dated 4/1/91); HED recommended the removal of TCP from the tolerance expression for CPM (PP#6F3429/6H5506, DEB No. 6969, M. Flood, 4/29/91). Therefore, tolerances for residues in/on plant and animal commodities are to be expressed in terms of parent CPM only.

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS 860.1000). As a result of changes to Table 1, additional CPM residue data are now required for some commodities; these data requirements have been incorporated into this document. These new data requirements will be imposed at the issuance of the CPM RED but should not impinge on the reregistration eligibility decisions for CPM. The need for revisions to dietary exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 4/16/99 indicated that there is one CPM end-use product (EP) registered to DAS with uses on food/feed crops. This EP label (Reldan® 4E, EPA Reg. No. 62719-43, accepted 2/99) is for a 4 lb/gal EC that may be applied as a coarse spray to a moving stream of grain at 3-6 ppm in 1-5 gallons of water or food grade mineral oils per 1000 bushels of grain; the label specifies that the high dose is used only when grain is stored ≥ 3 months. The label also permits the application of a 1% solution of CPM to the walls and floors of grain bins and warehouses prior to grain storage at a rate of 0.04 lb ai/650-1250 ft² diluted in one gallon of water. The number of applications allowed over the entire storage period is not specified.

A review of the EP label and supporting residue data indicate that the following label amendments are required:

- The label should be amended to specify that a maximum number of one application to stored grain commodities is permitted during the entire storage period.
- The label must be revised to require pretreatment testing of grain samples to verify that the grain has not been treated previously with CPM.

A tabular summary of the residue chemistry science assessments for reregistration of CPM is presented in Table A. The conclusions listed in Table A regarding the reregistration eligibility of CPM food/feed uses are based on the use patterns registered by the basic producer, DAS. When end-use product data call in's (DCIs) are developed (e.g., at issuance of the RED), the Registration Division (RD) should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's (DAS') labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on metabolism studies conducted on stored corn and wheat grain. HED had previously determined that TCP is no longer a residue of concern with respect to chlorpyrifos because of its inactivity as a cholinesterase inhibitor (E. Doyle, 4/1/91). Therefore, HED concluded that TCP need not appear in the tolerance expression, and that tolerances are to be expressed in terms of CPM *per se* (M. Flood, 4/29/91).

In the metabolism studies, corn and wheat were treated with ^{14}C -CPM to give a concentration of 32.4 ppm on the grain. Parent compound comprised >80% of the initial dose of ^{14}C -activity found on the day of treatment, and 19.1-62.3% in grain stored 30-180 days. Parent decreased with time with a corresponding increase in the major metabolites, TCP and the monoacid of CPM, which accounted for up to 31.2% and 19.7% of the initial ^{14}C -dose, respectively, in grains after 180 days of storage. Based upon the plant metabolism data, the phosphate ester undergoes extensive hydrolysis yielding products that are expected to have little or no cholinesterase inhibiting activity. Minor amounts ($\leq 0.6\%$ of the initial dose) of the S-methyl isomer were also detected.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of CPM residues in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. HED has determined that the CPM residues to be regulated in animal commodities will include CPM only.

In goat liver, kidney, and heart, the major residue was TCP which comprised 66.4-75.1% of the total radioactive residue (TRR); parent accounted for up to 2.9% of the TRR. In fat and milkfat, parent was the major component, accounting for 49-74%. The major terminal residues in poultry tissues and egg yolks were parent, TCP, and the monoacid. TCP and the monoacid accounted for 67.1 and 22.6% of the TRR in kidney, and up to 20.3 and 26.7% of the TRR in egg yolk, respectively. Parent was the principle residue in fat (74.8% TRR) and accounted for ~16% of the TRR in egg yolk. Minor amounts of the S-methyl isomer were also detected in animal tissues and milk.

OPPTS GLN 860.1340/1360: Residue Analytical Methods/Multiresidue Methods

The Pesticide Analytical Manual (PAM) Vol. II lists a GC/ECD method (Method I) that determines the combined residues of CPM and TCP in or on stored grain commodities following conversion of CPM to TCP *via* hydrolysis; residues of TCP are then derivatized prior to GC analysis. This method is not ideal for enforcement purposes because it is not capable of specifically determining residues of CPM *per se*; combined residues of CPM and TCP are measured.

However, adequate methodology is available to enforce tolerances for residues in/on plant commodities: The FDA PESTDATA database (PAM Vol. I, January 1994) indicates that CPM is completely recovered using FDA Multiresidue Protocols D and E (PAM I Sections 232.4 and 211.1). Residue data on stored grains and grain processed commodities were collected using adequate analytical methods (Methods ACR 78.18 and ACR 77.6(3), respectively) capable of determining CPM *per se*. The registrant should conduct an independent laboratory validation (ILV) for one of these methods and submit results to the Agency. The Agency will then conduct a tolerance method validation (TMV).

Briefly, residues in/on whole grains are extracted by shaking with acetone, centrifuged, diluted, and analyzed by GC using a flame photometric detector (FPD); the validated limit of quantitation (LOQ) for residues of CPM in/on whole grains is 1.0 ppm. Residues in processed fractions are extracted in the same manner, partitioned sequentially with hexane and acetonitrile (ACN), concentrated to remove the ACN, and redissolved in hexane. The residues are further purified on a silica gel column prior to analysis by GC/FPD. The method was validated using grain processed fractions (wheat grain, flour, and bran) to a lower limit of 0.01 ppm.

The GC/FPD method listed in PAM Vol. II (Method II) capable of determining residues of CPM *per se* in meat, milk, and eggs of livestock is adequate for enforcement of tolerances on animal commodities.

Data on residues of CPM *per se* in animal commodities have been collected using an adequate GC/FPD method (Method ACR 77.6.1) currently published in PAM II as Method II. Briefly, residues in muscle, liver, and kidney are extracted with acetone, filtered, concentrated, and partitioned into hexane; residues in fat are extracted with hexane. The residues are then partitioned with ACN, concentrated, redissolved in hexane, and cleaned-up on a silica gel column prior to analysis by GC/FPD. Using a modification of this method (Method ACR 77.6.s1), residues in milk or cream are heated to 45 C, extracted with a solution of methanol:hexane (1:1, v/v) and NaCl, and centrifuged. The residues are then purified and analyzed as described above for tissues. The method was validated by the registrant to a lower limit of 0.01 ppm using tissues and milk; however, as the Agency validated the method to a lower limit of 0.05 ppm, tolerances have been reassessed at 0.05 ppm.

The Agency previously concluded (DP Barcode D169228, J. Morales, 4/30/92) that CPM residues on stored corn grain could not practically be controlled by use label restrictions because stored grain can be moved from one location to another and treated at each location. To address the potential for over-tolerance residues resulting from multiple postharvest grain treatments using CPM, Gustafson has developed an immunoassay procedure to be used in grain storage areas to verify that grain has not been previously treated. The method, which can rapidly detect residues in excess of 0.1 ppm, was independently validated (DP Barcode D193346, M. Flood, 3/10/94) and has been successfully validated by the Agency's Analytical Chemistry Branch (DP Barcode D200683, M. Flood, 6/15/94). This method cannot be substituted for the Agency-validated, conventional analytical method required for enforcement purposes, but is suitable for pre-treatment testing.

Residue data for TCP in/on stored grains and livestock commodities are also available and were collected using adequate methodology. However, as TCP is no longer a residue of concern, these methods are not presented.

OPPTS GLN 860.1380: Storage Stability Data

Adequate storage stability data are available for the purposes of risk assessment. Although no storage stability data were submitted to support the residue studies, the existing storage stability data for chlorpyrifos suggest that residues of CPM are stable frozen in stored plant and animal matrices. The Residue Chemistry Chapter of the Chlorpyrifos Reregistration Standard (2/29/84) indicates that residues of chlorpyrifos are relatively stable (65-110% of the original fortification levels) in corn and sorghum matrices stored at -18 C for up to 27 months; likewise, residues of chlorpyrifos *per se* are stable (69-74% of the initial levels) in livestock commodities stored frozen for ~4 years. Confirmatory storage stability data on CPM are needed to confirm these assumptions.

As sample storage intervals were not reported in the magnitude of the residue studies, detailed sample histories should be submitted along with the required storage stability data. The petitioner reported that samples of plant and animal material were maintained frozen from collection to analysis.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Sufficient residue data are available on stored grain crops (barley, oats, rice, sorghum, and wheat) for the purposes of risk assessment. However, deficiencies in label use directions and storage stability need to be resolved, and confirmatory data supporting the residue studies on stored grains are required.

The available data are from a 1979 residue study in which samples of barley, corn, oat, rice, sorghum, and wheat grain were treated with CPM once at 6 ppm (1x rate) and analyzed for residues of CPM immediately following treatment and after storage intervals of 0 (up to 50 days

posttreatment), 1, 3, 6, and 12 months. Residues of CPM *per se* were 4.3-7.0 ppm in/on one sample each of barley (5.4 ppm), corn (4.3 ppm), oats (5.2 ppm), rice (7.0 ppm), and wheat (5.5 ppm) grain analyzed immediately after treatment. [HED notes that the rice residue value of 7.0 ppm is above the 1 X application rate (would be considered a violative sample, therefore, the rice HAFT that will be used is 6.0 ppm]

Data are needed from three studies depicting residues of CPM in/on treated wheat grain stored in CPM-treated storage facilities and sampled on the day of treatment following applications at the maximum use rate. The trials should include the use of both water and mineral oil as the spray diluent. The current labels allow treatment of storage facilities prior to storage of treated grain, and data reflecting this potential “worse-case” scenario were not provided by the original residue studies.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants - Pending Petitions

There is currently one active petition pending from DowElanco pertaining to use of CPM on stored corn grain (PP#6F3429/6H5506). This petition is currently in reject status based upon deficiencies in label directions and proposed tolerances (DP Barcode D186441, J. Morales, 6/2/93 and DP Barcode D200683, M. Flood, 6/15/94).

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

As part of the DAS response (7/19/99, MRID 449069, D259302) to HED’s preliminary risk assessment (G. Bangs, 9/20/99, D259632), the registrant stated that HED did not utilize all of the available processing data in the acute and chronic dietary analyses (S. Law, 6/8/99, D256070). Although the processing data were previously reviewed by HED (R. Perfetti, 3/13/81), new processing factors were calculated beyond those identified in the original review. If more than one processing study was conducted on the same raw agricultural commodity (RAC), then the average processing factor was calculated from the studies. The calculated processing factors used for the specific Dietary Exposure Evaluation Model (DEEM™) food forms in these dietary assessments are discussed below.

Additionally, residue reduction factors obtained from cooking studies reported in the open literature (Cogburn, et. al., “Fate of Malathion and Chlorpyrifos-Methyl in Rough Rice and Milling Fractions Before and After Parboiling and Cooking,” *Journal of Economic Entomology*, **83** (4): 1636-1639, 1990. and Nakamura, et. al., “Reductions in Postharvest-Applied Dichlorvos, Chlorpyrifos-methyl, Malathion, Fenitrothion, and Bromide in Rice during Storage and Cooking Processes,” *J. Agricultural and Food Chemistry*, **41**: 1910-1915, 1993) were incorporated into the dietary exposure analysis (Table 1.a). A residue reduction factor of 0.026 X was calculated for boiled commodities; a residue reduction factor of 0.36 X was calculated for baked/fried commodities. These reduction factors were applied to all of the RAC boiled and baked/fried food forms.

Table #1.a. Processing/Cooking Data.

Reference	Crop	Application Rate (ppm)	Processed Fraction	Residue Detected (ppm)	Processing Factor
Cogburn et al.	Rice	6	Rough rice	4.45	
			Hulls	14.9	3.3
			Brown rice	0.87	0.2
			Bran	6.1	1.4
			Milled rice	0.14	0.03
			Cooked	0.06	0.013
Nakamura et al.	Rice	Intended Use (from polished rice)		<u>% Remaining</u>	
			Polished rice	100*	
			Washed rice	18	0.018
		Boiled rice	Boiled rice	3.8	0.038
		Noodles	Polished rice	100*	
			Washed rice	16.7	0.17
			Rice powder	16.7	0.17
			Raw noodle	3.1	0.031
			Steamed noodle	2.1	0.021
			Rice noodle	<1	<0.01

*CPM applied directly to the polished rice.

Wheat

See Table 1.b. for a summary of wheat processing data.

Wheat-rough - uncooked: Applied a 0.86 X (the “after cleaning” processing factor shown below) reduction factor to the wheat-rough, uncooked food form.

Wheat-germ and germ oil: Applied a 2.7 X (the “wheat germ” processing factor shown below) concentration factor.

Wheat-bran: Applied a 3 X (average of “wheat bran” processing factors given below) concentration factor.

Wheat-flour: Applied a 0.15 X (average of “wheat flour” processing factors given below) reduction factor.

As previously noted, the residue reduction factor of 0.026 X was incorporated for boiled commodities and the residue reduction factor of 0.36 X was incorporated for baked/fried commodities (Cogburn, et. al., and Nakamura, et. al.). These reduction factors were applied to all of the wheat RAC boiled and baked/fried food forms.

Table #1.b. Wheat Processing/Cooking Data.

MRID	Crop	Application Rate (ppm)	Measured Concentration (ppm)	Processed Fraction	Residue Detected (ppm)	Processing Factor
00042608	Wheat	6	5.2	Flour	0.41	0.08
				Bran	11	2.1
				Red dog	6.9	1.3
				Germ	14	2.7
				Shorts	17	3.3
				Cookies	0.22	0.04
000161588	Wheat	4.5	3.6	Flour	0.69	0.19
				Bran	11.3	3.1
				Shorts	6.72	1.9
				Whole meal	3.53	0.98
				Whole meal bread	1.2	0.33
				White bread	0.29	0.08
	Wheat	9.0	6.8	After cleaning	5.68	0.84
				Flour	1.24	0.18
				Bran	25	3.7
				Shorts	14.4	2.1
				Whole meal	7.23	1.1
				Whole meal bread	2.65	0.39
				White bread	0.52	0.08

Barley

Used the residue reduction factor of 0.026 X for boiled commodities; used the residue reduction factor of 0.36 X for baked/fried commodities (Cogburn, et. al., and Nakamura, et. al.). These reduction factors were applied to all of the barley RAC boiled and baked/fried food forms.

Table #1.c. Barley Processing Data.

MRID	Crop	Application Rate (ppm)	Measured Concentration (ppm)	Processed Fraction	Residue Detected (ppm)	Processing Factor
00042607	Barley	6	4.1	Malt	0.28	
				Spent grain	0.39	
				Filter aid	<0.01	
				Yeast	ND	
				Malt cleaning	0.23	
				Cleanser overs	2.4	
				Cleanser thrus	19	
				Beer	ND	

Oats

Oats: Applied a 0.24 X reduction factor to account for the processing of whole oats to oak flakes.

Oat-bran: Applied a 2.8 X concentration factor based on available data for oat hulls.

As previously noted, the residue reduction factor of 0.026 X for boiled oat and oat bran commodities and 0.36 X for baked/fried oat and oat bran commodities was applied (Cogburn, et. al., and Nakamura, et. al.). These reduction factors were applied to all of the oat and oat bran boiled and baked/fried food forms.

Table #1.d. Oat Processing Data.

MRID	Crop	Application Rate (ppm)	Measured Concentration (ppm)	Processed Fraction	Residue Detected (ppm)	Processing Factor
00042606	Oats	6	3.6	Hulls	10	2.8
				Groat	1.1	0.31
				Flakes	0.87	0.24
				Disc Rejects	1.2	0.33
				Light Oats	16	4.44
				Dust	61	16.9

Rice

Rice-rough: As previously noted, the residue reduction factor of 0.026 X for boiled commodities was applied; the residue reduction factor of 0.36 X for baked/fried commodities was applied (Cogburn, et. al., and Nakamura, et. al.). These reduction factors were applied to all of the rice RAC boiled and baked/fried food forms.

Rice-milled: Applied a 0.07 X (average of "white rice" processing factors given below) reduction factor.

Rice-bran: Applied a 1.7 X (average of "rice bran" processing factors given below; the 0.45 processing factor was not included in the average because it was not in the range of the other two processing factors given) concentration factor.

Table #1.e. Rice Processing Data.

MRID	Crop	Application Rate (ppm)	Measured Concentration (ppm)	Processed Fraction	Residue Detected (ppm)	Processing Factor
00042609	Rice	6	4.4 (27 days)	Hulls	16	3.6
				Brown rice	0.89	0.2
				White rice	0.62	0.14
				Bran	2.0	0.45
				Grits	2.2	0.5
00042610	Rice	6	6.2 (7 days)	Hulls	20	3.2
				Brown rice	1.9	0.3
				White rice	0.26	0.04
				Bran	11	1.8
		6	4.8 (14 days)	Hulls	18	3.8
				Brown rice	1.5	0.31
				White rice	0.14	0.03
				Bran	7.8	1.6

Processed Commodity Tolerances

Pending resolution of storage stability issues, the reregistration requirements for magnitude of CPM residues in processed food/feed commodities are fulfilled for stored grain commodities.

Currently, tolerances are established for the combined residues of CPM and TCP in milled fractions (exc. flour) of barley, oats, rice, sorghum, and wheat at 30-120 ppm. These tolerances were determined based on the proposed tolerances for the grain (6.0 ppm) and the highest concentration factor found for the combined residues in any processed grain fraction. In the following reassessment, conducted accordingly to current HED policy, tolerances were

determined using the concentration factor for residues in each regulated processed commodity and the highest average field trial (HAFT) residues for the specified grain. The HAFT residues for parent are from the 1979 study on stored grains in which one sample of each grain commodity was analyzed immediately following one treatment with CPM at 6.0 ppm.

The available wheat processing study indicates that residues of CPM *per se* concentrate in bran (3x), and germ and germ oil (2.7x), but do not concentrate in flour (S. Levy, D259807, 10/28/99). Based on the concentration factors and HAFT residues of 5.5 ppm, the tolerance for residues of CPM in wheat bran and germ should be established at 20 ppm.

The available processing study on barley does not provide residue data on pearled barley, flour or bran; however, data from the wheat processing study are translatable to barley. Based on the HAFT residues of 5.4 ppm in barley grain, and a concentration factor of 3x for bran (from wheat bran), a tolerance for residues of CPM *per se* should be established in barley bran at 20 ppm (S. Levy, D259807, 10/28/99).

The available oat processing study indicates that residues of CPM *per se* concentrate on average by 2.8x in hulls (S. Levy, D259807, 10/28/99). Tolerances for residues of CPM *per se* should be established at 15 ppm in oat hulls based on HAFT residues of 5.2 ppm.

The available rice processing study indicates that residues of CPM *per se* concentrate on average by 1.7x in bran and by 4x in hulls (S. Levy, D259807, 10/28/99). Tolerances for residues of CPM *per se* should be established at 12.5 ppm in rice bran and 25.0 ppm in rice hulls based on the respective bran concentration factors and HAFT residues of 6.0 ppm.

When separate tolerances are established for the appropriate processed commodities, the tolerance for CPM residues in barley, oats, and rice milled fractions should be revoked.

Flour is the only sorghum processed commodity currently regulated; however, OPPTS.GLN 860.1000 (Table 1) indicates that residue data on sorghum flour are not needed at this time as it is used exclusively in the U.S. as a component for drywall, and not as either a human food or livestock feed. In addition, the sorghum processing study demonstrated that residues of CPM do not concentrate appreciably (1.4x) in sorghum flour. The tolerance for residues of CPM in milled fractions of sorghum (excluding flour) should be revoked.

Data from the corn processing study indicate that CPM residues in/on corn aspirated grain fractions are 84x higher than in/on corn grain (PP#6F3429, DP Barcode D169228, J. Morales, 4/30/92). Additional data depicting the potential for concentration of CPM residues in/on aspirated grain fractions derived from sorghum and wheat are required.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. Adequate poultry, ruminant, and swine feeding studies are available depicting residues of CPM *per se* in meat, milk, poultry and eggs. Based upon the anticipated residues (ARs) of the RACs, the *acute* and *chronic* calculated dietary burdens for livestock are 1.3 ppm for beef and dairy cattle, 1.1 ppm for hogs, and 0.05 ppm for poultry and are presented in Table #2.

The tolerance determined for aspirated grain fractions (AGF) will have a substantial impact on the dietary burden. A tolerance of at least 400 ppm, used in calculating the dietary burdens shown below, will be required for CPM residues in/on AGF, based upon the 84x concentration factor and HAFT residues of 4.3 ppm in corn grain. However, this tolerance cannot be assessed until AGF data are available on wheat and sorghum. If significantly higher residues are found in wheat or sorghum aspirated grain fractions, a new feeding study may be required. Note that the available processing study on oats indicates that CPM residues concentrate by 16x in oat dust.

Table #2. Calculation of acute and chronic dietary burdens of livestock animals for CPM.

Feed Commodity	% Dry Matter ^a	% Diet ^a	Anticipated Residue (ppm) ^b	Acute Dietary Contribution (ppm) ^c	Chronic Dietary Contribution (ppm) ^d
Beef and Dairy Cattle					
wheat grain	89	20	0.06	0.013	0.013
corn forage	88	60	0	0	0
aspirated grain fractions	85	20	5.04	1.19	1.19
TOTAL BURDEN		100		1.3	1.3
Poultry					
wheat grain	N/A	80	0.06	0.048	0.048
soybean meal	N/A	20	0	0	0
TOTAL BURDEN		100		0.05	0.05
Swine					
wheat grain	N/A	80	0.06	0.048	0.048
aspirated grain fractions	N/A	20	5.04	1.01	1.01
TOTAL BURDEN		100		1.1	1.1

^a Table 1 (OPPTS.GLN 860.1000).

^b RAC anticipated residue (AR) according to Table # 6. The AR for aspirated grain fractions = RAC AR (0.06 ppm) * Concentration Factor (84x).

^c Acute Dietary Contribution = [tolerance / % DM (if cattle)] X % diet).

^d Chronic Dietary Contribution = [tolerance / % DM (if cattle)] X % diet).

In the ruminant feeding study, at a feeding level of 100 ppm (~ 77 x), uncorrected residues of CPM in beef tissues and milk were as follows: muscle and liver (<0.01 ppm), kidney (0.03 ppm), fat (0.61 ppm) and cream (0.40 ppm, reflecting 0.03 ppm in whole milk). These data indicate that the tolerances for residues of CPM *per se* in cattle, goats, horses, and sheep should be lowered to 0.05 ppm for muscle and meat byproducts, and increased to 1.0 ppm for fat; the tolerances for residues in milkfat and milk, 1.25 ppm for milkfat (reflecting 0.05 ppm in whole milk), are adequate. Table #3 summarizes the ruminant ARs to be used for meat, meat byproducts, meat fat and milk in the acute and chronic dietary exposure analysis.

Table # 3. Maximum Acute and Chronic AR Values [at 100 pm (77 X) extrapolated to (1 X)] in Ruminant Tissues.

TISSUE	ACUTE and CHRONIC ARs ^a
Muscle	0.0001
Liver	0.0001
Kidney	0.0004
Fat	0.008
Milk Fat	0.005
Milk (whole)	0.0004

^a Acute and Chronic AR = Study Residue Value (ppm) / 77 X.

In the hog feeding study, at a feeding level of 100 ppm (~ 1.2 x), residues of CPM were 0.13 ppm in muscle, <0.01 ppm in liver and kidney, and 0.74 ppm in fat. These data indicate that the tolerance for residues in fat should be increased to 1.0 ppm, and that the tolerances for residues in meat and mbypr should be lowered to 0.15 ppm and 0.05 ppm, respectively. Table #4 summarizes the hog ARs to be used for meat, meat byproducts and meat fat in the acute and chronic dietary exposure analysis.

Table # 4. Maximum Acute and Chronic AR Values [at 100 pm (91 X) extrapolated to (1 X)] in Hog Tissues.

TISSUE	ACUTE and CHRONIC ARs ^a
Muscle	0.001
Liver	0.00009
Kidney	0.00003
Fat	0.007

^a Acute and Chronic AR = Study Residue Value (ppm) / 91 X.

In the poultry feeding study, hens were dosed with CPM at 0, 10 (200 x), 30 (600 x) or 100 (2000 x) ppm. At the 10 ppm dose, residue levels were <0.01 ppm in muscle, liver, fat and eggs. At the 30 ppm dose, residue levels were < 0.01 ppm in muscle, liver and eggs; in fat the residue level was 0.01 ppm. At the 100 ppm dose, residue levels were 0.01 ppm in muscle, <0.01 ppm in liver, 0.08 ppm in fat and 0.02 ppm in eggs. Based on these data, the established tolerances for residues of CPM in poultry should be lowered to 0.01 ppm in muscle, mbyp, and eggs, and 0.05 ppm in fat. Table #5 summarizes the poultry ARs to be used for meat, meat byproducts, meat fat and eggs in the acute and chronic dietary exposure analysis.

Table # 5. Maximum Acute and Chronic AR Values [at 100 pm (2000 X) extrapolated to (1 X)] in Poultry Tissues.

TISSUE	ACUTE AR ^a
Muscle	0.000005
Liver	0.000005
Fat	0.00004
Eggs	0.00001

^a Acute and Chronic AR = Study Residue Value from Dosing at 100 ppm / 2000 X.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

CPM is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics. [CPM is registered on rice strictly for post-harvest treatment of stored rice grain.]

OPPTS GLN 860.1460: Magnitude of the Residue in Food-handling Establishments

CPM is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

As CPM is restricted to use on stored grains and grain storage facilities, no residue chemistry data are required under these guideline topics.

ANTICIPATED RESIDUES FOR DIETARY RISK ASSESSMENT

Pesticide Data Program (PDP)

CPM data from the USDA PDP Monitoring program are available (1995-1997) for wheat and milk. When choosing which data set to use for a Monte Carlo assessment, the order of preference is generally PDP data > FDA data > field trial data. In general, monitoring data is preferred over field trial data because it is sampled longer after harvest and is therefore more reflective of residues consumed "at the dinner plate"; PDP data is preferred over FDA data because of the statistical design of the PDP program specific for dietary risk assessment. Monitoring data can be "decomposed" prior to use in acute dietary risk assessment; however, this is not necessary for CPM because the raw agricultural commodities (RACs) in which it is used on are considered "blended" commodities (HED SOP 99.6, 8/20/99).

Out of 1,562 wheat monitoring samples from PDP (1995-1997), 920 samples had detectable CPM residues (approximately 60% with detectable residues); see Table #6 for details. In general, the FDA Surveillance Monitoring data (1992-1998) supported the percentage of detections found in wheat by PDP, both quantitatively and qualitatively. The wheat PDP residue values should be translated to the other RACs (barley, oats, rice and sorghum) because the use pattern of CPM is the same. Because wheat is considered to be a nationally blended commodity, the average PDP residue value, calculated using $\frac{1}{2}$ the limit of detection (LOD) for samples not having measurable residues, from 1995-1997 monitoring should be used in both the acute and chronic dietary exposure assessments.

Out of 1,297 monitoring data samples from PDP (1996-1997) for milk, there were no detectable CPM residues in any samples; see Table #7 for details. Milk is not considered to be a nationally blended commodity, therefore, for the acute assessment, the 1996-1997 PDP residue values (all non-detectable residues, therefore $\frac{1}{2}$ the average LODs [range= 0.001-0.002 ppm]) should be incorporated directly into a residue distribution file (RDF). For the chronic assessment, the milk AR is the average of the 1996-97 PDP data (all non-detectable residues, therefore $\frac{1}{2}$ the average LODs were used [range= 0.001-0.002 ppm]). Meat is not considered to be a nationally blended commodity either. Usually, for meat and milk the highest feed item's (from the RAC) percent crop treated (%CT) value is used either in DEEM™'s adjustment factor #2 column or inserted probabilistically to refine the residue values. However, this should not be done in this assessment because of the discrepancy between Biological Economic Analysis Division's (BEAD's) %CT information ($\leq 9\%$ for all RAC's; electronic correspondence, T. Kiely, 5/18/99) and the percent detects found in the PDP monitoring program (approximately 60%). Therefore, as a conservative approach, 100 %CT should be assumed for meat and milk.

Table #6. Summary of Wheat PDP Data.

Crop	Year	# of Samples Analyzed	# of Detects	% of Detects	Minimum Concentration Detected (ppm)	Maximum Concentration Detected (ppm)	Average of Detectable Residues (ppm)	LOD (ppm)
Wheat	1995	600	325	54	0.002	3.322	0.11	0.001
Wheat	1996	340	249	73	0.002	1.525	0.09	0.001
Wheat	1997	622	346	56	0.002	1.796	0.11	0.001

Table #7. Summary of Milk PDP Data.

Crop	Year	# of Samples Analyzed	# of Detects	% of Detects	Minimum Concentration Detected (ppm)	Maximum Concentration Detected (ppm)	Average of Detectable Residues (ppm)	OD Range (ppm)
Milk	1996	570	0	0	-	-	-	0.001-0.002
Milk	1997	727	0	0	-	-	-	0.001-0.002

FDA Total Diet Study

The FDA Total Diet Study (TDS), sometimes called the Market Basket Study, is an ongoing FDA program that determines levels of various pesticide residues, contaminants, and nutrients in foods, for the purpose of estimating intakes of these substances in representative diets of specific age-sex groups in the United States population. To accomplish this goal, FDA personnel purchase foods from supermarkets or grocery stores four times per year, one from each of four geographic regions of the country. Each collection, referred to as a Market Basket (MB), is a composite of like foods purchased in three cities in a given region. The foods are prepared for consumption, i.e., as they will be eaten, and then analyzed.

Starting with MB 91-3, 260 foods were included in TDS. Since then, several foods have been removed or added to accommodate availability. A total of 264 different foods are represented in the 18 MBs analyzed since that time.

It is important to an accurate understanding of TDS to realize that many of the food items are prepared recipes rather than a single food. For example, "apple, red, raw" is a food item and another is "lasagna with meat, homemade". In all cases, whether the item is a simple uncooked food or a prepared recipe, each ingredient is purchased in three different cities within the same region and each of the final food items is prepared for consumption. Before analysis, the three individual portions are combined. An appropriate aliquot of each combination is then taken for each analyses prescribed for that food.

As can be seen from these results, nearly all products analyzed that contained processed commodities derived from grains (flour, bran, etc.) had measurable CPM residues in most of the 18 MBs. The following commodities had measurable residues in all 18 of the MBs conducted from 1991-1997: fish sticks, frozen, heated; white roll; whole wheat bread; tortilla, flour; rye bread; cracked wheat bread; English muffin, toasted; butter-type crackers; fish sandwich, fast food; pretzels, hard, salted; teething biscuits.

The Agency typically does not use TDS results quantitatively in dietary exposure assessments, rather the data are used qualitatively. The results of the TDS can provide additional information that complements PDP and FDA Surveillance Monitoring program results. TDS results for chlorpyrifos-methyl are summarized in Attachment 1.

For the purposes of dietary risk assessment, acute and chronic ARs for CPM have been calculated for barley, oats, rice, sorghum, grain, meat, milk, poultry and eggs; see summary Table #8. Wheat data were translated to the other grains.

Table #8. Acute and Chronic ARs¹ and Processing Factors used for Dietary Risk Assessment.

Commodity	Acute AR ² (ppm)	Chronic AR ³ (ppm)
Barley, grain	0.06	0.06
Oats, grain	0.06	0.06
Rice, grain	0.06	0.06
Sorghum, grain	0.06	0.06
Wheat, grain	0.06	0.06
Fat of cattle, goats, horses and sheep	0.008	0.008
Meat of cattle, goats, horses and sheep	0.0001	0.0001
Liver of cattle, goats, horses and sheep	0.0001	0.0001
Kidney of cattle, goats, horses and sheep	0.0004	0.0004
Hogs, fat	0.007	0.007
Hogs, muscle	0.001	0.001
Hogs, mby	0.00009	0.00009
Milk	0.0008	0.0008
Milk, fat ⁴	0.009	0.009
Poultry, fat	0.00004	0.00004
Poultry, meat	0.000005	0.000005
Poultry, liver	0.000005	0.000005
Eggs	0.00001	0.00001

¹ Modified acute and chronic ARs for dietary risk assessment from CPM Residue Chemistry Chapter (S. Law, 6/8/99, D256666).

² The acute dietary risk assessment should utilize the entire distribution of monitoring data (PDP) for the RAC incorporating ½ the LOD (for treated non-detects) to calculate the average residue (the PDP LOD = 0.001 ppm for all 3 years). For the acute milk AR, the monitoring data (PDP) should be incorporated into a RDF (all non-detectable residues, therefore ½ the average LODs were used [range= 0.001-0.002 ppm]). For the meat, poultry and egg ARs, the AR should be incorporated into an RDF. No further adjustment should be made for meat, milk, poultry or egg %CT.

³ The chronic dietary risk assessment should utilize the monitoring data (PDP) for the RAC incorporating ½ the LOD (for treated non-detects) to calculate the average residue (the PDP LOD = 0.001 ppm for all 3

years). The chronic milk AR given here is the average residue values from the 1996-97 PDP data (all non-detectable residues, therefore $\frac{1}{2}$ the average LOD should be used [range= 0.001-0.002 ppm]). No further adjustment should be made for meat, milk, poultry or egg %CT.

4 The milk fat acute and chronic AR was re-evaluated since the previous CPM Residue Chemistry Chapter (S. Law, 6/8/99, D256666). Upon re-evaluation, it was noted that chlorpyrifos-methyl residues concentrate by 13 X in milk, cream. Therefore, the milk AR (0.0008 ppm) was adjusted to reflect the 13 fold concentration in milk, cream (0.009 ppm).

Table A. Residue Chemistry Science Assessments for Reregistration of CPM.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References
860.1200: Directions for Use	N/A	Yes ¹	See Section 860.1200
860.1300: Plant Metabolism	N/A	No	00114290 ²
860.1300: Animal Metabolism	N/A	No	00114291 ² 00114292 ² 00114293 ² 00114294 ²
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00042611 ³ 00042612 ³ 00042618 ³ 42852701 ⁴
- Animal commodities	N/A	No	00042613 ³ 00042616 ³ 00042617 ³
860.1360: Multiresidue Methods	N/A	No	See p. 4; FDA Multiresidue Protocols D and E (PAM I Sections 232.4 and 211.1)
860.1380: Storage Stability Data	N/A	Yes ⁵	
860.1500: Crop Field Trials			
<u>Cereal Grains Group</u>			
- Barley, grain	6.0 [§180.419]	Yes ⁶	00042599 ³
- Oats, grain	6.0 [§180.419]	Yes ⁶	00042599 ³
- Rice, grain	6.0 [§180.419]	Yes ⁶	00042599 ³
- Sorghum, grain	6.0 [§180.419]	Yes ⁶	00042599 ³
- Wheat, grain	6.0 [§180.419]	Yes ⁶	00042599 ³
<u>Miscellaneous Commodities</u>			
- Aspirated Grain Fractions	None	Yes ⁷	42017101 ⁸
860.1520: Processed Food/Feed			
- Barley, milled fractions (exc. flour)	90.0 [§185.1050] [§186.1050]	No	00042607 ³
- Oats, milled fractions (exc. flour)	130.0 [§185.1050] [§186.1050]	No	00042606 ³

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References
- Rice, milled fractions (exc. flour)	30.0 [§185.1050] [§186.1050]	No	00042609 ³ 00042610 ³
- Sorghum, milled fractions (exc. flour)	90.0 [§185.1050] [§186.1050]	No	00042604 ³
- Wheat, milled fractions (exc. flour)	30.0 [§185.1050] [§186.1050]	No	00042608 ³
860.1480: Meat, Milk, Poultry, and Eggs			
- Meat, Meat-by-products, and fat of cattle, goats, hogs, horses, and sheep	0.5 [§180.419]	No	00042596 ³ 00042600 ³ 00042601 ³
- Milk	0.05 [§180.419]	No	00042603 ³
- Milk, fat	1.25 [§180.419]	No	00042603 ³
- Meat and Meat-by-products of poultry	0.5 [§180.419]	No	00042602 ³
- Eggs	0.1 [§180.419]	No	00042602 ³
860.1400: Water, Fish, and Irrigated Crops	None	No	
860.1460: Food Handling	None	N/A	
860.1850: Confined Rotational Crops	N/A	N/A	
860.1900: Field Rotational Crops	None	N/A	

1. Based upon the available residue data and/or changes in data requirements, the Agency is recommending changes to use directions. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under Directions for Use.
2. PP#0F2423 and /FAP#0H5277, DP Barcode [None], R. Perfetti, 1/25/83
3. PP#0F2423 and /FAP#0H5277, DP Barcode [None], R. Perfetti, 3/13/81
4. DP Barcode D193346, M. Flood, 3/10/94
5. Sample storage intervals and conditions for the residue trials on stored grains, processed commodities, and livestock are required. If the samples were analyzed ≥ 30 days after collection, supporting storage stability

data are required. Storage stability data submitted for chlorpyrifos reregistration suggest that residues of CPM are probably stable frozen in plant and animal matrices; however, confirmatory data on CPM that support the storage intervals and conditions of the residue studies are required.

6. Confirmatory data supporting the results of the original residue studies on stored grains are required. Data are needed from three studies depicting residues of CPM in/on wheat grain stored in CPM-treated storage facilities and sampled on the day of treatment after application at the maximum use rate. The trials should reflect the use of both water and mineral oils as the spray diluent. If the samples are stored frozen for >30 days prior to analysis, the residue studies should be accompanied by supporting storage stability data.
7. Data are required depicting CPM residues in/on aspirated grain fractions (grain dust) derived from wheat and sorghum grain treated with CPM. RAC samples should be treated using both water and mineral oil as diluents. Adequate corn grain dust data are available indicating that CPM residues in/on corn grain dust were 84x higher than in/on corn grain.
8. PP#6F3429, CBTS No. 11149, DP Barcode D169228, J. Morales, 4/30/92.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for CPM residues are currently expressed as the combined residues of CPM and TCP in or on plant and animal commodities [40 CFR §180.419]. HED has concluded that the U.S. tolerance expression should be amended to include only CPM *per se* (M. Flood, 4/29/91). Accordingly, the tolerance definition for CPM should be amended to include only parent CPM. In addition, the food and feed additive tolerances for *grain milled fractions (exc. flour)* listed separately under 40 CFR §185.1050 and §186.1050 should be revoked concomitant to establishing the appropriate tolerances, noted below, for residues of CPM in processed commodities under 40 CFR §180.419.

A summary of the CPM tolerance reassessment for the above commodities and recommended modifications in commodity definitions are presented in Table B.

Tolerances Listed Under 40 CFR §180.419:

Provided that (i) the requested label amendments are made, (ii) questions concerning the storage stability of CPM are resolved, and (iii) confirmatory residue data on stored grains are submitted, sufficient data are available to reassess tolerances for CPM residues in/on barley, oats, rice, sorghum, and wheat. The established tolerances are adequate for CPM residues in/on stored grains of barley, oats, rice, sorghum and wheat.

Provided that storage stability concerns are addressed, sufficient data are available to reassess tolerances for CPM residues in poultry tissue and eggs. Based on the dietary burden for poultry (6.0 ppm), and data from poultry feeding and metabolism studies, the established tolerances for residues of CPM in poultry should be lowered to 0.01 ppm in muscle, mbyp, and eggs, and 0.05 ppm in fat.

Sufficient data are available for a risk assessment on residues of CPM in cattle, goats, hogs, horses, and sheep commodities. However, the tolerances cannot be reassessed at this time because residue data on aspirated grain fractions derived from treated wheat and sorghum are required. Data from the available corn processing study indicate that a tolerance of at least 400 ppm will be needed for residues of CPM in aspirated grain fractions (the dietary burdens noted for cattle and swine include this contribution). If significantly higher residues are found in wheat or sorghum aspirated grain fractions, a new ruminant feeding study may be required.

The dietary burden for beef and dairy cattle (100 ppm) and the data from the ruminant feeding study support increasing the tolerances for CPM residues in fat of cattle, horses, goats, and sheep to 1.0 ppm, and lowering the tolerances for CPM residues in meat and mbyp to 0.05 ppm. The available data indicate that established tolerances for milk and milkfat are adequate.

Based on the dietary burden for swine of 85 ppm, the data from the hog feeding study support increasing the tolerance for residues in fat to 1.0 ppm, and lowering the tolerances for residues in meat and mbyp to 0.15 ppm and 0.05 ppm, respectively.

Tolerances Listed Under 40 CFR §185.1050 and §186.1050 :

Tolerances for residues of CPM in milled fractions (excluding flour) of barley, rice, sorghum, and wheat should be revoked concomitant with establishing separate tolerances for residues in the appropriate processed commodities under 40 CFR §180.419 (see next section).

Tolerances Needed Under 40 CFR §180.419:

New tolerances are needed for CPM residues in/on aspirated grain fractions. A tolerance of at least 400 ppm will be required for CPM residues in/on aspirated grain fractions, based upon the 84x concentration factor and current HAFT residues of 4.3 ppm in/on corn grain. However, this tolerance cannot be assessed until aspirated grain fraction data on sorghum and wheat are available.

A tolerance of 20 ppm is required for CPM residues in barley bran based upon the 3x concentration factor (translated from wheat) and HAFT residues of 5.4 ppm in/on barley grain.

Tolerances for residues of CPM *per se* should be established at 25 ppm in rice hulls and 12.5 ppm rice bran based on concentration factors of 4x and 1.7x, respectively, and HAFT residues of 6.0 ppm.

Based on the concentration factor of 2.8x in hulls and HAFT residue of 5.2 ppm in/on oat grain, the tolerance for residues of CPM *per se* should be established in oat bran at 17.0 ppm.

Based on the concentration factors of 3x in bran, and 2.7x in germ and HAFT residues of 5.5 ppm in/on wheat grain, a tolerance for residues of CPM *per se* should be established in wheat bran and wheat germ at 20 ppm.

Once the necessary separate tolerances are established for residues in processed commodities, the feed/food additive tolerances for residues in milled fractions (exc. flour and oats) of barley, and wheat under §185.1050 and §186.1050 should be revoked. As residue data on sorghum processed fractions are no longer required, the tolerance for residues in sorghum milled fractions should also be revoked.

Table B. Tolerance Reassessment Summary for CPM.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR §180.419:			
Barley, grain	6.0	6.0	
Oats, grain	6.0	6.0	
Rice, grain	6.0	6.0	
Sorghum, grain	6.0	6.0	Sorghum, grain, grain
Wheat, grain	6.0	6.0	
Fat of cattle, goats, hogs, horses, & sheep	0.5	TBD ^a	Tolerances cannot be reassessed at this time because residue data on aspirated grain fractions derived from treated wheat and sorghum are required. Aspirated grain fractions contribute significantly to the dietary burden for cattle and swine. If significantly higher residues are found in wheat or sorghum aspirated grain fractions, then a new ruminant feeding study may be required.
Meat and meat byproducts of cattle, goats, horses, & sheep	0.5		
Hogs, muscle	0.5		
Hogs, meat byproducts	0.5		
Milk	0.05		
Milk, fat	1.25		
Poultry, fat	0.5	0.05	Residue data support lowering the tolerances established on poultry commodities.
Poultry, meat byproducts	0.5	0.01	
Poultry, meat	0.5	0.01	
Eggs	0.1	0.01	
Tolerances listed under 40 CFR §185 and §186.1050:			
Barley, milled fractions (excluding flour)	90.0	Revoke	Tolerance should be revoked concomitant with establishing a 20 ppm tolerance on <i>barley bran</i> .
Oats, milled fractions	130.0		Tolerance should be revoked concomitant with establishing a ppm tolerance for <i>oat bran</i> .
Rice, milled fractions (excluding flour)	30.0		Tolerance should be revoked concomitant with establishing tolerances on <i>rice bran</i> (12.5 ppm).
Sorghum, milled fractions (excluding flour)	90.0		Tolerance should be revoked. There are no longer any processed commodities of grain sorghum considered as food for humans or feed for livestock.
Wheat, milled fractions (excluding flour)	30.0		Tolerance should be revoked concomitant with establishing a tolerance on <i>wheat bran</i> , <i>wheat germ</i> and <i>germ oil</i> at 20 ppm.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances needed under 40 CFR §180.419			
Aspirated Grain Fractions	None	TBD ^a	The available data on corn support a tolerance of <u>at least</u> 400 ppm. Additional data are required for sorghum and wheat
Barley, bran	90.0	20.0	Concomitant with revoking the tolerance for barley milled fractions, a tolerance on <i>barley bran</i> should be established
Rice, bran	30.0	12.5	Concomitant with revoking the tolerance for rice milled fractions, a tolerance on <i>rice bran</i> should be established.
Rice, hulls	None	25.0	Concomitant with revoking the tolerance for rice milled fractions, a tolerance on <i>rice bran</i> should be established.
Oat, bran	None	17.0	Concomitant with revoking the tolerance for oat milled fractions, a tolerance on <i>oat, bran</i> should be established.
Wheat, bran	30.0	20.0	Concomitant with revoking the food/feed additive tolerance for wheat milled fractions, a tolerance on <i>wheat, bran</i> should be established.
Wheat, germ	30.0	20.0	Concomitant with revoking the food/feed additive tolerance for wheat milled fractions, a tolerance on <i>wheat, germ</i> should be established.

^a TBD = To be determined. Tolerances cannot be determined at this time because additional data are required.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for CPM residues in/on various plant and animal commodities. The Codex MRLs and U.S. tolerances are not compatible because the U.S. tolerance expression currently includes the parent CPM and its metabolite, TCP. However, HED has recommended that the U.S. tolerance expression be amended to include only CPM (M. Flood, 4/29/91). Once the U.S. tolerance definition is amended, it will be compatible with the definition for Codex MRLs.

A comparison of the Codex MRLs (from *Guide to Codex Maximum Limits for Pesticide Residues*, Updated 4/99) and the corresponding U.S. tolerances is presented in Table C. The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

Once the U.S. tolerance definition is amended to include only CPM, U.S. tolerances and Codex MRLs would be compatible for wheat bran, meat and edible offal of cattle, meat and edible offal of chicken, and eggs.

Based upon the use patterns registered in the U.S. and the available residue data, compatibility of U.S. tolerances and Codex MRLs is not currently possible for the following crops/commodities: barley, cattle fat, chicken fat, milk, oats, rice, sorghum, wheat and wheat processed commodities (except bran). Codex has postponed discussion on MRLs for cereal commodities pending review of additional residue data on these commodities.

Table C. Codex MRLs for chlorpyrifos-methyl and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Apple	0.05	CXL	None	Not registered for this use in the U.S.
Artichoke globe	0.1	CXL		
Barley	10.0 ^a	6 ^b	6.0	U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm.
Cabbages, Head	0.1	CXL	None	Not registered for this use in the U.S.
Cattle fat	0.05	CXL	0.5	Data for aspirated grain fractions are required before US tolerance can be reassessed
Cattle, meat	0.05	CXL	0.5	Data for aspirated grain fractions are required before US tolerance can be reassessed
Cattle, Edible offal of	0.05	CXL	0.5	U.S. tolerance is for <i>meat byproducts</i> . Data for aspirated grain fractions are required before US tolerance can be reassessed
Chicken, fat	0.05	CXL	0.05	
Chicken, meat	0.05	CXL	0.01	U.S. residue data support lower tolerance.
Chicken, Edible offal of	0.05	CXL	0.01	U.S. tolerance is for <i>meat byproducts</i> . U.S. residue data support lower tolerance.
Chinese cabbage	0.1	CXL	None	Not registered for these uses in the U.S.
Common bean	0.1	CXL		
Date	0.05	CXL		
Egg plant	0.1	CXL		
Eggs	0.05	CXL	0.01	U.S. residue data support lower tolerance.
Grapes	0.2	CXL	None	Not registered for these uses in the U.S.
Lettuce, Head	0.1	CXL		
Milk	0.01 ^c	CXL	0.05	Data for aspirated grain fractions are required before US tolerance can be reassessed
Mushrooms	0.01 ^c	CXL	None	Not registered for this use in the U.S.
Oats	10.0 ^a	6 ^b	6.0	U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm.
Oranges, Sweet, Sour	0.5	CXL	None	Not registered for these uses in the U.S.
Peach	0.5	CXL		
Peppers	0.5	CXL		

Table C. Continued.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Radish	0.1	CXL		
Rice	0.1	CXL		
Rice	10.0 ^a	6(a) ^b	6.0	U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm.
Sorghum	10.0 ^a	CXL	6.0	U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm.
Tea, Green, Black	0.1	CXL	None	Not registered for these uses in the U.S.
Tomato	0.5	CXL		
Wheat	10.0 ^a	CXL	6.0	U.S. residue data indicate that the lower tolerance is adequate. Use pattern in U.S. specifies to apply up to 6.0 ppm.
Wheat bran, Unprocessed	20.0 ^d	CXL	20.0	
Wheat flour	2.0 ^a	CXL	None	U.S. residue data indicate that a separate tolerance for wheat flour is not required.
White bread	0.5 ^d	CXL	None	Not a regulated commodity in the U.S.
Wholemeal bread	2.0 ^d	CXL	None	Not a regulated commodity in the U.S.

^a Accommodates post-harvest treatment of commodity.

^b Codex discussions on MRLs for cereal commodities have been postponed pending review of all residue and processing studies available on cereal commodities and estimation of IEDIs.

^c MRL set at or about the limit of determination.

^d Accommodates post-harvest treatment of the primary food commodity.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode: None
Subject: PP#0F2423/0H5277. Chlorpyrifos-methyl on Grains. Evaluation of Analytical Methods and Residue Data.
From: R. Perfetti
To: J. Ellenberger
Dated: 3/13/81
MRID(s): None cited

DP Barcode: None
Subject: PP#0F2423/0H5277. Chlorpyrifos-methyl on Stored Grains.
From: R. Perfetti
To: J. Ellenberger
Dated: 1/25/83
MRID(s): None cited

DP Barcode: None
Subject: Clarification of Chlorpyrifos Reregistration Standard - Revision to Exclude TCP Metabolite from Existing Tolerances.
From: E. Doyle
To: R. Schmitt
Dated: 4/1/91
MRID(s): None cited

CBTS No.: 6969
DP Barcode: None
Subject: PP#6F3429/6H5506 Chlorpyrifos-methyl in/on Stored Grain. Amendment to Remove TCP from Tolerance Expression.
From: M. Flood
To: D. Edwards
Dated: 4/29/91
MRID(s): None cited

CBTS No.: 11149
DP Barcode: D169228
Subject: PP#6F3429. Chlorpyrifos-methyl on Corn Dust. Amendment of 8/18/86.
From: J. Morales
To: D. Edwards
Dated: 4/30/92
MRID(s): 42017101

DP Barcode: D186441
Subject: 6F3429/6H5506: Chlorpyrifos-methyl on corn grain. Amendment in response to review of 4/30/92.
From: J. Morales
To: D. Edwards/C. Andreasen
Dated: 6/2/93
MRID(s): None cited

DP Barcode: D193346
Subject: 6F3429/6H5506: Chlorpyrifos-methyl in Stored Grain. Independent Lab Validation of Test Kit.
From: M. Flood
To: D. Edwards/C. Andreasen
Dated: 3/10/94
MRID(s): 42852701

CBTS No.: 130810
DP Barcode: D200683
Subject: 6F3429/6H5506: Chlorpyrifos-methyl (Reldan 4E®) in/on Stored Corn Grain. Results of EPA Method Validation.
From: M. Flood
To: D. Edwards/C. Andreasen
Dated: 6/15/94
MRID(s): None cited

DP Barcode: D256666
Subject: Chlorpyrifos-methyl. Product and Residue Chemistry Chapters of the RED.
From: S. Law
To: M. Hartman
Dated: 6/8/99
MRID(s): None cited

DP Barcode: D256070
Subject: Chlorpyrifos-methyl: Acute and Chronic Dietary Exposure Analyses.
From: S. Law
To: M. Hartman
Dated: 6/8/99
MRID(s): None cited

DP Barcode: D259632
Subject: Chlorpyrifos-methyl. Preliminary Risk Assessment.
From: G. Bangs
To: S. Nguyen
Dated: 9/20/99
MRID(s): None cited

DP Barcodes: D259302, D259871, D260042
Subject: Response to: Dow AgroSciences' Response to U.S. EPA's Preliminary Risk Assessment for Chlorpyrifos-Methyl, Health Effects Division FQPA Reassessment Chapter Dated July 19, 1999
From: G. Bangs/S. Levy/J. Doherty
To: S. Nguyen
Dated: 10/7/99
MRID(s): 449069

DP Barcode: D259807 (Linked with D259806)
Subject: Chlorpyrifos-Methyl: Revised Acute and Chronic Dietary Exposure Analyses.
From: S. Levy
To: S. Nguyen
Dated: 11/28/99
MRID(s): None cited

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Attachment 1: FDA Total Diet Study, Summary of Chlorpyrifos-Methyl Residues Found, Market Basket Surveys From 1991-4th quarter to 1997-1st Quarter - A total of 18 market basket surveys were conducted over this time period.

Chlorpyrifos-Methyl

<u>Residue Item# Description</u>	<u>n</u>	Food Level Found, ppm		
		<u>Mean</u>	<u>Min</u>	<u>Max</u>
034 fish sticks, frozen, heated	18	0.0021	0.0006	0.006
051 oatmeal, cooked	7	0.0015	0.0004	0.004
052 wheat cereal, farina, cooked	2	0.001	0.001	0.001
058 white bread	17	0.0081	0.001	0.029
059 white roll	18	0.0084	0.001	0.024
060 cornbread, homemade	10	0.0023	0.0006	0.005
061 biscuit, baked	15	0.0032	0.001	0.009
062 whole wheat bread	18	0.0322	0.008	0.14
063 tortilla, flour	18	0.006	0.0008	0.025
064 rye bread	18	0.0113	0.001	0.073
065 blueberry muffin	16	0.0066	0.0007	0.025
066 saltine crackers	17	0.0166	0.001	0.047
068 pancake from mix	15	0.0076	0.001	0.024
069 egg noodles, boiled	16	0.0034	0.001	0.009
070 macaroni, boiled	11	0.0024	0.001	0.006
072 fruit-flavored cereal	4	0.0012	0.0009	0.002
073 shredded wheat cereal	8	0.0141	0.001	0.033
074 raisin bran cereal	11	0.0054	0.001	0.015
076 granola cereal	13	0.0322	0.0006	0.137
077 oat ring cereal	3	0.0103	0.001	0.018
142 spaghetti and meatballs	3	0.002	0.002	0.002
146 macaroni and cheese, box	14	0.0022	0.0007	0.006
147 hamburger, fast-food	16	0.0026	0.0004	0.007
149 spaghetti, canned	4	0.0015	0.001	0.002
151 lasagna with meat	3	0.0011	0.0004	0.002
152 chicken potpie, frozen	16	0.006	0.0006	0.018
156 tomato soup, canned	4	0.0012	0.0009	0.002
160 white sauce, homemade	3	0.0026	0.0008	0.004
178 chocolate cake and icing	11	0.0024	0.001	0.005
179 yellow cake with white icing	11	0.0023	0.0007	0.005
182 sweet roll or Danish	15	0.0047	0.001	0.018
183 chocolate chip cookies	11	0.009	0.0008	0.03
184 sandwich cookies creme fill	14	0.0069	0.0006	0.018
185 apple pie	17	0.0085	0.003	0.018
186 pumpkin pie	17	0.0044	0.001	0.013
241 chicken nuggets, fast-food	5	0.0016	0.0005	0.005
242 chicken, fried fast-food	1	0.0009	0.0009	0.0009
247 mixed nuts, no peanuts	1	0.002	0.002	0.002
248 cracked wheat bread	18	0.0178	0.007	0.039
249 bagel, plain	17	0.0094	0.001	0.037
250 English muffin, toasted	18	0.0064	0.001	0.019
251 graham crackers	17	0.0122	0.002	0.052

252 butter-type crackers	18	0.0099	0.001	0.056
269 beef stroganoff	14	0.0017	0.0005	0.005
272 tuna noodle casserole	12	0.0011	0.0005	0.002
273 salisbury steak, frozen meal	4	0.0012	0.0009	0.002
274 turkey, frozen meal	1	0.001	0.001	0.001
275 cheeseburger, fast-food	16	0.0031	0.0006	0.008
276 fish sandwich, fast-food	18	0.0034	0.0008	0.007
277 frankfurter, fast-food	15	0.0035	0.0009	0.011
278 egg/cheese/ham, fast-food	16	0.0037	0.0008	0.017
279 taco or tostada, carry-out	6	0.0011	0.0005	0.002
280 cheese pizza, carry-out	17	0.0062	0.001	0.02
281 pepperoni pizza, carry-out	17	0.0052	0.001	0.019
282 beef chow mein, carry-out	3	0.0027	0.002	0.004
284 mushroom soup, canned	1	0.001	0.001	0.001
285 clam chowder, canned	2	0.0009	0.0008	0.001
289 chocolate snack cake	12	0.0034	0.001	0.006
290 cake doughnuts with icing	17	0.0066	0.001	0.032
291 brownies, commercial	13	0.0055	0.0008	0.016
292 sugar cookies, commercial	15	0.0129	0.001	0.045
294 pretzels, hard, salted	18	0.0236	0.0004	0.08
301 brown gravy, homemade	5	0.0018	0.0009	0.003
317 teething biscuits	18	0.0272	0.001	0.265
	749			



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Chemical: Chlorpyrifos-methyl (ANSI)

PC Code: 059102

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